Niagara™ Slim-Cath™ Short-Term Dialysis Catheter

510(k) Summary of Safety and Effectiveness Information
21CFR 807.92

1. Submitter Information:

Submitter Name:	Bard Access Systems, Inc. [Subsidiary of C. R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700, Ext. 4903
Fax Number:	(801) 595 5425
Contact Person:	Peggy Keiffer
Date of Preparation:	March 14, 2001

2. Device Name:

Device Name:	Niagara™ Slim-Cath™ Short-Term Dialysis Catheter
Trade Name:	Niagara ™ Slim-Cath™
Common/Usual Name:	Short-Term Hemodialysis Catheter
Classification Name:	78 MPB – Catheter, Hemodialysis, Non-implanted 21 CFR 876.5540(b)(2) – Non Implanted Blood Access Device

3. Predicate Device Name:

Device Name:	Niagara™ Short-Term Dialysis Catheter
Trade Name:	Niagara ™
Common/Usual Name:	Short-Term Hemodialysis Catheter
Classification Name:	78 MPB – Catheter, Hemodialysis, Non-implanted 21 CFR 876.5540(b)(2) – Non Implanted Blood Access Device

4. Device Description:

The device description of the Niagara Slim-Cath Short Term Dialysis Catheter is as follows:

- The Niagara Slim-Cath Catheter is available in 12 French straight and precurved configurations. The insertion lengths are as follows:
  Straight: 15, 20 and 24 centimeters
  Precurved: 12.5, 15, 20 centimeters
- The catheter shaft is made from soft aliphatic polyurethane, and contains barium sulfate to provide radiopacity.

- The catheter shaft has two round lumens positioned side by side. The arterial lumen is beveled. The venous lumen extends beyond the arterial lumen at the distal end to form a rounded lumen and ends with a soft atraumatic black tip made from a softer polyurethane.
- A nylon stiffening stylet is provided in the venous lumen.
- The extension legs are made from aromatic polyurethane. On each extension is an atraumatic clamp and colored luer connectors identifying the arterial (red) and venous (blue) lumens.
- A rotatable flexible PVC suture wing is in place on the shaft near the exit site for securing the catheter after initial placement, and a removable silicone suture wing is provided for the clinician's optional use.
- The catheter insertion length is printed on the bifurcation.
- The priming volumes are printed on the extension legs.
- Five - one centimeter depth markings are provided distal to the bifurcation. The 5 depth markings in one (1) cm increments may be used to determine insertion depth. The insertion line (just below rotatable suture wing) represents total insertion length.

5. Intended Use:

Niagara Dual Lumen Catheters are indicated for use in attaining short term (less than 30 days) vascular access for hemodialysis, hemoperfusion, or apheresis therapy via the jugular, subclavian, or femoral vein.

6. Technological Characteristics Summary:

6.1 Does the new device have the same indication statement?

Yes.

6.2 Does the new device have the same technological characteristics, eg. design, material, etc.?

Not in all respects. The principles of operation and basic design are equivalent. The French size is different, but the insertion lengths are the same. The material for both is polyurethane but the durometers slightly differ (new device is slightly stiffer). The stylet is different from the predicate, but the same as other stylets currently cleared for use in a different catheter family with the same intended use. Depth markings have been added and other minor design changes have been made.

6.3 Could the new characteristics affect safety or effectiveness?

Yes. All of the above unique features could affect the safety or effectiveness of the device.

6.4 Do the new characteristics raise new types of safety and effectiveness questions?

No. The safety and effectiveness questions are the same for all short-term dialysis catheters.

6.5 Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. The FDA's "Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95, and corresponding ISO Standards were used to evaluate the device's performance.

Biocompatibility meets the requirements of ISO-10993, " Biological Evaluation of Medical Devices Part-1: Evaluation and Testing: and the FDA Modified ISO 10993 Test Profile for their intended use.

6.6 Are performance data available to assess effects of new characteristics?

Yes. Bench testing was performed according to the above referenced standards. The results of the testing were compared to the predicate devices. The test results met the requirements. In addition, competitive product evaluation was performed comparing the Niagara Slim-Cath to the Mahurkar catheter.

6.7 Do performance data demonstrate equivalence?

Yes. Performance data demonstrate that the Niagara™ Slim-Cath™ Short-Term Dialysis Catheter is substantially equivalent to the predicate Niagara™ Short-Term Dialysis Catheters.

6.8 Performance Data (if applicable).

Tests performed per Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95:
Dimensions
Flow rates
Tensile strength of catheter body
Tensile strength of catheter body to hub attachment
Catheter Stiffness
Catheter Tip (distal) attachment strength
Catheter elongation
Leakage at hub
Catheter burst pressure (positive internal pressure)
Catheter collapse (negative internal pressure)
Catheter Flexural fatigue tolerance

Additional Catheter Tests:
Kink testing
Forward and reverse recirculation
Hemolysis
Rotatable suture wing attachment test

Additional Stylet Tests:
Cytotoxicity

Hub tensile
Dimensions
Guidewire fit test
Stylet removal Test

Additional Biocompatibility Testing (for the Ink)
Cytotoxicity
Hemocompatibility
Physicochemical Test (includes heavy metals)
Systemic Injection
Ames Genotoxicity
Cytotoxicity (material aged 5 years)
Hemocompatibility – (material aged years)

The Niagara Slim-Cath short term dialysis catheters meet all the acceptance criteria of the testing performed and, based on FDA's decision tree, are substantially equivalent to the predicate device, the Niagara short term dialysis catheters, K965178, cleared August 19, 1997.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 3 2001

Ms. Peggy Keiffer
Regulatory Affairs Manager
Bard Access Systems, Inc.
C. R. Bard, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K010778
Niagara™ Slim-Cath™ Short-Term Dialysis Catheters
Dated: March 14, 2001
Received: March 15, 2001
Regulatory Class: II
21 CFR §876.5540/Procode: 78 MPB

Dear Ms. Keiffer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

FDA notes that your device will contain sutures for which you have provided evidence that the suture characteristics are not altered by the sterilization process used for the device. However, you should be aware of the following additional information regarding the inclusion of a suture as a component of your device:

1. The labeling, packaging and method of sterilization of the suture cannot be changed without prior notification, review and clearance by FDA.

2. The supplier of the sutures used in your device cannot be changed without prior notification, review and clearance by FDA.

In addition, we have determined that your device kit contains PVP swab sticks and Lidocaine, 1%, which are subject to regulation as drugs.

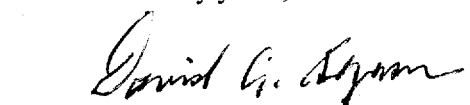
Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR §807.97). Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION(S) FOR USE STATEMENT*

I state in my capacity as Regulatory Affairs Specialist of Bard Access Systems, that this notification [510(k)] for the following devices, Niagara Slim-Cath Short-Term Dialysis Catheters, are indicated for the following:

Niagara Dual Lumen Catheters are indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis, hemoperfusion, or apheresis therapy via the jugular, subclavian, or femoral vein.

Signature of 510(k) Submitter: Peggy Keiffer

Printed Name of Submitter: Peggy Keiffer

Date: 3.14.01

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

Concurrence of Office of Device Evaluation

510(k) Number _____

Division Sign-Off
Office of Device Evaluation

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT and Radiological Devices
510(k) Number K010778

Prescription Use ✓ **OR** **Over-The-Counter Use** _____